REMARKS

The present response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 1-45 are pending in the application. Claims 1-20 have been rejected. Claims 21-45 were withdrawn. No claim canceled herein. Claims 1, 3, 4, 9, 11, 15, and 16 are amended herein. Support for this amendment can be found, at least, in the claims as filed.

CLAIM REJECTIONS

35 U.S.C. § 103 Rejections

Rejection over Siegel

In the Office Action, the Examiner rejected claims 1-13, 15, and 17-20, under 35 U.S.C. § 103(a), as allegedly being obvious over Siegel (U.S. Patent Application Publication No. 2002/0179096) ("Siegel"). Specifically, the Examiner asserts that Siegel teaches an implantable device for the long term delivery of a therapeutic agent as claimed. Applicants respectfully disagree for the reasons set forth below.

Applicants note that Applicants have amended independent claim 1, and the amended claim recites "biodegradable polymer comprises a poly(lactide/glycolide) (PLGA) copolymer at a concentration of about 40-90% (w/w)" and "drug comprises risperidone, 9-OH-risperidone, or an active metabolite thereof at a concentration of about 10-60% (w/w)." Nowhere does Siegel describe or teach this combination of claimed feature. Rather, Siegel relates to haloperidol loading with polylactide or lactide-co-glycolide copolymer. In fact, the Examiner acknowledges that Siegel does not teach risperidone. *See* page 6, lines 14-15 of the Office Action.

Since Siegel does not describe or teach the above discussed claimed feature, Siegel cannot render the claimed invention obvious, and thus this rejection is believed moot. Accordingly, Applicants respectfully request removal of this rejection.

Rejection over Siegel in view of Sidman

In the Office Action, the Examiner rejected claims 13 and 14, under 35 U.S.C. § 103(a), as allegedly being obvious over Siegel in view of Sidman (U.S. Patent 4,352,337) ("Sidman"). In response, Applicants note that claims 13 and 14 are dependent claims that ultimately depend from and add additional features to independent claim 1. Since independent claim 1 is patentable for the reasons discussed above, dependent claims 13 and 14 are also patentable by virtue of there dependency. Accordingly, Applicants respectfully request removal of this rejection.

Rejection over Siegel in view of Kino

In the Office Action, the Examiner rejected claim 16, under 35 U.S.C. § 103, as allegedly being obvious over Siegel in view of Kino et al (U.S. Patent No. 5,871,778) ("Kino"). Specifically, the Examiner asserts that Siegel teaches a surgically implantable drug delivery device for long-term delivery of the antipsychotic drug – haloperidol. The Examiner acknowledges that Siegel does not teach risperidone, but relies on Kino for this feature. Accordingly, the Examiner finds that it would have been obvious to combine the references to arrive at the invention. Applicants respectfully disagree for the reasons set forth below.

As discussed above, Applicants have amended independent claim 1, and the amended claims recite "biodegradable polymer comprises a poly(lactide/glycolide) (PLGA) copolymer at a concentration of about 40-90% (w/w)" and "drug comprises risperidone, 9-OH-risperidone, or an active metabolite thereof at a concentration of about 10-60% (w/w)." Nowhere does Siegel describe or teach this claimed feature. Rather, Siegel relates to haloperidol loading with polylactide or lactide-co-glycolide copolymer.

Kino relates only to bromperidol or haloperidol loaded into dl-Polylactic acid or Poly(lactic-co-glycolic)acid (50:50) for making a microcapsule, which is not an implant as claimed. Although Kino describes a laundry list of active materials including risperidone, it provides no data or support for how much of each active ingredient that can be loaded in to each biodegradable polymer. Therefore, at the maximum, Kino provides a general guidance for producing only a microcapsule with no expectation of success with respect to specific amount of drug for each combination of the drug and the polymer.

Applicants note that it would be unreasonable to expect initial theoretical drug concentrations of 10% or more due to possible saturation and subsequent crystallization of the drug. Therefore, an attempt to incorporate as much as 10-60% risperidone into the PLA:PGA copolymer, as claimed in the subject Application cannot be expected in view of the Kino reference or any other reference in the art. Accordingly, it would not have been obvious to modify Siegel's implant based on the Kino's laundry list of active materials.

Furthermore, in the subject Application, surprisingly and unexpectedly, the invention changes the matrix degradation and affects the release rates. As shown in the Application, higher risperidone loading concentration stabilizes the system, slowing the release rate.

Since Kino does not teach or suggest how to arrive at the claimed 10%-60% risperidone and 40%-90% of the biodegradable polymer, Kino does not render the claimed invention obvious.

Accordingly, neither Siegel nor Kino, either alone or in combination, teach or suggest all the features of the claimed invention. Therefore, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

/Mark S. Cohen/

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